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510(k) Summary

Device: Kinemax® Plus Modular Stabilizer Femoral Component
and Femoral Spacers

Common Name: Modular Femoral Component and Femoral Spacers

Classification Name and Reference: 21 CFR 888.3560
Knee Joint patellofemorotibial semi-constrained cemented
prosthesis

Proposed Regulatory Class: Class II

Device Product Code: JWH OR(87)

The Kinemax® Plus Modular Stabilizer Femoral Component and Femoral Spacers are intended to be used with Kinemax® and Kinemax® Plus tibial and patellar components as a total knee system. These components are intended to be used in total knee replacement procedures indicated due to inflammatory or non-inflammatory joint disease, failed previous prosthesis, or trauma.

Specifically, this femoral component is intended to be used in situations where a stemmed component is desired to provide additional stability. This femoral component allows the surgeon to use (as an option) femoral spacers to augment bone loss on the distal or distal/posterior surfaces of the femur.

These components are intended to be implanted using bone cement.

The Kinemax® Plus Modular Stabilizer Femoral Component and Femoral Spacers are substantially equivalent to several other legally marketed devices. Examples of these are listed below:

1. Kinemax® Plus Stabilizer Femoral Component (Howmedica - K910500)
2. Duracon® Stemmed Stabilizer Femoral Component (Howmedica - K932070)
3. Duracon® Femoral Spacers (Howmedica - K920034)

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